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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/641,983	08/17/2000	Michael L. Lehrman	ILIF01-00056	6192
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/641,983	Applicant(s) LEHRMAN ET AL.	
	Examiner Amanda R. Flynn	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 7, 10-14, 16, 17, 20-25 and 27-29 is/are rejected.
- 7) ☒ Claim(s) 5, 8, 9, 15, 18, 19 and 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 20-21 and 28-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13, 15, 23-25 of U.S. Patent No. 6,666,830 ('830) in view of U.S. Patent Number 4,715,367 to Crossley.

'830 discloses at least an apparatus for terminating a physiological process that causes partially occluded breathing to occur in an airway of a person due to a partial obstruction of said airway due to an obstructive sleep apnea event, wherein said physiological process is terminated

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before cessation of breathing occurs, wherein the apparatus comprises: at least one microphone capable of being acoustically associated with said person, said microphone capable of detecting breathing sounds within said airway of said person and capable of generating signals representative of said breathing sounds; a controller coupled to said at least one microphone and capable of receiving said signals, said controller capable of identifying within said signals at least one signal pattern that is associated with a partially occluded breathing pattern of said person that occurs at the onset of said physiological process before cessation of breathing occurs.

'830 also discloses at least a method for terminating a physiological process that causes partially occluded breathing to occur in an airway of a person due to a partial obstruction of said airway due to an obstructive sleep apnea event, wherein said physiological process is terminated before cessation of breathing occurs, said method comprising the steps of: detecting breathing sounds within said airway of said person; generating signals representative of said breathing sounds; identifying within said signals at least one signal pattern that is associated with a partially occluded breathing pattern of said person that occurs at the onset of said physiological process before cessation of breathing occurs; recording said at least one signal pattern that is associated with a partially occluded breathing pattern of said person that occurs at the onset of said physiological process before cessation of breathing occurs; monitoring said signals representative of said breathing sounds as said person breathes; comparing said signals representative of said breathing sounds with said recorded at least one signal pattern that is associated with a partially occluded breathing pattern of said person that occurs at the onset of said physiological process before cessation of breathing occurs; identifying within said signals a signal pattern that is substantially the same as said recorded at least one signal pattern that is

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associated with a partially occluded breathing pattern of said person that occurs at the onset of said physiological process before cessation of breathing occurs. '830 does not specify that the apparatus or method include generating and alarm and stimulating the person's neck to terminate the partially occluded breathing.

Crossley discloses an apparatus and method for terminating partially occluded breathing caused by a sleep apnea event that involves sensing the onset of a sleep apnea event and generating an alarm signal in the form of a stimulus applied to the person's neck, to terminate the event.

It would have been obvious to one skilled in the art at the time the invention was made to have provided the apparatus and method disclosed by '830, wherein the apparatus and method stimulate the person's neck, as taught by Crossley, to terminate the apnea event.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 2, 6-7, 10-12, 16-17, 20-22, 25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Number 5,123,425 to Shannon, Jr. et al. in view of U.S. Patent Number 4,715,367 to Crossley.

Shannon, Jr. et al. disclose an apparatus for terminating a physiological process (sleep apnea) that causes cessation of breathing to occur in an airway of a person due to a complete obstruction of said airway due to an obstructive sleep apnea event, wherein said physiological

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process is terminated before complete cessation of breathing occurs, wherein the apparatus comprises: at least one microphone (24) capable of being acoustically associated with said person, said microphone capable of detecting breathing sounds within said airway of said person and capable of generating signals representative of said breathing sounds. The microphone detects the presence of breath OR it detects snoring sounds, and generates an electrical signal representative of such (see column 3, lines 25-30 and column 4, lines 19-42). Shannon, Jr. et al. also specifies that instead of a microphone an air flow sensor can be utilized to obtain information concerning the breathing of the person. Shannon, Jr. et al. disclose a controller (20) coupled to the microphone and capable of receiving said signals. A filter (204) is coupled between the microphone and the controller, wherein the filter is capable of filtering said signals from the microphone to create filtered signal representative of said breathing or snoring sounds. The controller is capable of identifying within the filtered signals at least one signal pattern (a pattern of said snoring sounds) that is associated with a breathing pattern of said person that occurs at the onset of said physiological process (as evidenced by Crossley, which discloses a link between snoring sounds and the onset of an apnea event), before cessation of breathing occurs, and is capable of generating an alarm signal in response thereto. A stimulus generator (26, 28) is coupled to the controller, the stimulus generator being capable of receiving said alarm signal from said controller, and in response thereto, creating an electrical current stimulus that is applied to said person to terminate said physiological process before cessation of breathing occurs. The controller of the apparatus is further structurally capable of operating only during one half of the respiration cycle, or for whatever portion of the respiration cycle it is desired by

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the user to have functional operation. Shannon, Jr. et al. do not specify that the stimulus created by the stimulus generator be applied to the person's neck muscles.

Crossley discloses an apparatus for terminating a sleep apnea event that comprises a microphone that detects breathing and snoring sounds. The apparatus includes a stimulus generator that applies a stimulus to the patient's motor nerve in the neck, upon the detection of a sleep apnea event, such stimulus being capable of causing the patient's neck muscles to move the patient's head back and terminate the apnea event.

It would have been obvious to one skilled in the art at the time the invention was made to have provided the apparatus disclosed by Shannon, Jr. et al., wherein the stimulus created by the stimulus generator is applied to the patient's neck, as taught by Crossley, to terminate the apnea event. The method claimed is made obvious by the normal use of the apparatus as disclosed by Shannon, Jr. et al. in view of Crossley.

5. Claims 3-4, 13-14 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shannon, Jr. et al. in view of Crossley in view of U.S. Patent Number 5,652,566 to Lambert.

Shannon, Jr. et al. in view of Crossley disclose the previously described apparatus for terminating a sleep apnea event comprising a stimulus generator that applies a stimulus to a person's neck, to terminate a sleep apnea event. Shannon et al. in view of Crossley does not specify that the stimulus be vibratory or audible.

Lambert discloses an alarm generator that produces a vibratory or audible stimulus (24) to ensure that the user is stimulated. The references are analogous since they are from the same field of endeavor, the medical monitoring arts.

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It would have been obvious to one skilled in the art at the time the invention was made to have provided the apparatus disclosed by Shannon, Jr. et al. in view of Crossley, with the vibratory or audible alarm, as taught by Lambert, to provide alternate or additional alarm systems, insuring that the user is stimulated. Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary. The method claimed is made obvious by the normal use of the apparatus as disclosed by Shannon, Jr. et al. in view of Crossley in further view of Lambert.

Response to Arguments

6. Applicant's arguments with respect to claims 1-29 have been considered but are moot in view of the new ground(s) of rejection.

7. It is further noted, per MPEP section 2114: "While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997) (The absence of a disclosure in a prior art reference relating to function did not defeat the Board's finding of anticipation of claimed apparatus because the limitations at issue were found to be inherent in the prior art reference); see also In re Swinchart, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971); In re Danly, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original).

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8. A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987) (The preamble of claim 1 recited that the apparatus was "for mixing flowing developer material" and the body of the claim recited "means for mixing ..., said mixing means being stationary and completely submerged in the developer material". The claim was rejected over a reference which taught all the structural limitations of the claim for the intended use of mixing flowing developer. However, the mixer was only partially submerged in the developer material. The Board held that the amount of submersion is immaterial to the structure of the mixer and thus the claim was properly rejected.)."

Allowable Subject Matter

9. Claims 5, 8-9, 15, 18-19 and 26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda R. Flynn whose telephone number is 703-306-4056. The examiner can normally be reached on Monday-Thursday, 8:30 - 6:00 and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda R. Flynn
Examiner
Art Unit 3743

arf



Henry Bennett
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